R. N. LABORATORIES PVT. LTD.

Plot No.1 & 86, Sursez, Diamond Park, Sachin, Surat, Gujarat, India.

Certificate of Analysis

Section-A

Product Name	ChlorhexidineGluconate 20 % Solution (Pharma Grade)		
Reference	USP/EP/BP	AR. No.	FP/I/20/0233
Batch No.	RN1/CHG/20/20/149	Batch Size	8000 Kg.
Mfg. Date	18/04/2020	Exp.Date	17/04/2023
Release Date	22/04/2020		

Section-A: Chemical testing Section-B: Microbial testing

Sr. No.	Tests	Specification	Reference	Results
1.	Description	Almost colorless or pale yellowish, clear liquid.	USP/EP/BP	A clear colorless liquid.
2.	Solubility	Miscible with glacial acetic acid and with water; miscible with three times its volume of acetone and with five times its volume of dehydrated alcohol; further addition of acetone or dehydrated alcohol yields a white turbidity.	USP	Complies
		Miscible with water, with not more than 3 parts of acetone and with not more than 5 parts of ethanol (96%).	EP/BP	Complies
3.	IDENTIFICATION:			
	A. IR	The IR Spectrum obtained with sample should correspond with that of standard.	USP/EP/BP	Complies
	B. Thin Layer Chromatography	The principal spot in the chromatogram obtained with the test solution should be similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.	USP/EP/BP	Complies
	C. Residual melting Point	132°C to 136°C.	EP/BP	134.2°C
	D. Chemical Test	A deep red color should be produced.	EP/BP	Complies
4.	Specificgravity/ Relative density	1.06 to 1.07	USP/EP/BP	1.065

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Mr. Vikas Pathak	Mr. Vimal Patel	Mr. Niraj Choudhary
DESIGNATION	Officer QC	Assistant Manager QC	Assistant Manager QA/RA
SIGNATURE			
DATE	22/04/2020	22/04/2020	22/04/2020

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Plot No.1 & 86, Sursez, Diamond Park, Sachin, Surat, Gujarat, India.

Certificate of Analysis

Section-A

Product Name	ChlorhexidineGluconate 20 % Solution (Pharma Grade)		
Reference	USP/EP/BP	AR. No.	FP/I/20/0233
Batch No.	RN1/CHG/20/20/149	Batch Size	8000 Kg.
Mfg. Date	18/04/2020	Exp.Date	17/04/2023
Release Date	22/04/2020		

Sr. No.	Tests	Specification	Reference	Results
5.	pH(5% v/v)	5.5 to 7.0	USP/EP/BP	6.35
6.	Organic impurities (Related substances)			
	Chlorhexidineoxazinone analog (Impurity L)	NMT 0.2 %	USP/EP/BP	BDL
	Specified unidentifiedimpurity 1 (Impurity Q)	NMT 0.2 %	USP/EP/BP	BDL
	Chlorhexidine amine (Impurity G)	NMT 0.3 %	USP/EP/BP	BDL
	Chlorhexidine guanidine (Impurity N)	NMT 1.0 %	USP/EP/BP	BDL
	Chlorhexidine urea (Impurity B)	NMT 0.2 %	USP/EP/BP	BDL
	p-Chlorophenyl urea (Impurity F)	NMT 0.2 %	USP/EP/BP	BDL
	Chlorhexidine nitrile (Impurity A)	NMT 0.4 %	USP/EP/BP	BDL
	Chlorhexidine dimer (Impurity H)	NMT 0.5 %	USP/EP/BP	BDL
	o-Chlorhexidineandspecifiedunidentifiedimpurity 2 (Sum of Impurity I & O)	NMT 0.4 %	USP/EP/BP	BDL
	Chlorhexidineglucityl Triazine (Impurity J)	NMT 0.4 %	USP/EP/BP	BDL
	Chlorhexidine	-	USP/EP/BP	-

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Mr. Vikas Pathak	Mr. Vimal Patel	Mr. Niraj Choudhary
DESIGNATION	Officer QC	Assistant Manager QC	Assistant Manager QA/RA
SIGNATURE			
DATE	22/04/2020	22/04/2020	22/04/2020

R. N. LABORATORIES PVT. LTD.

Plot No.1 & 86, Sursez, Diamond Park, Sachin, Surat, Gujarat, India.

Certificate of Analysis

Section-A

Product Name	ChlorhexidineGluconate 20 % Solution (Pharma Grade)		
Reference	USP/EP/BP	AR. No.	FP/I/20/0233
Batch No.	RN1/CHG/20/20/149	Batch Size	8000 Kg.
Mfg. Date	18/04/2020	Exp.Date	17/04/2023
Release Date	22/04/2020		

Sr. No.	Tests	Specification	Reference	Results
	Oxochlorhexidine (Impurity K)	NMT 0.4 %	USP/EP/BP	BDL
	Any individual unspecified impurity	NMT 0.10 %	USP/EP/BP	BDL
	Total impurities	NMT 3.0 %	USP/EP/BP	BDL
7.	p –Chloroaniline	Not more than 500 ppm	USP	35.76 ppm
8.	Assay	NLT 19.0 % (w/v) and NMT 21.0 % (w/v)	USP	20.10 % w/v
		NLT 190 g/L and NMT 210 g/L	EP/BP	198.5 g/L
Residual Solvent				
9.	Methanol	Not more than 3000 ppm	Inhouse	212.66 ppm
10.	Butanol	Not more than 5000 ppm	Inhouse	43.28 ppm
11.	Colour absorbance test by UV at 480nm 1% w/v Solution	NMT 0.005	Inhouse	0.002

BDL= below disregard limit; ND= Not detected

If present, o-chlorhexidine and specified unidentified impurity 2 may not be completely resolved by the method. These peaks are integrated together to determine conformance.

Report: In the opinion of the undersigned, the above batch complies with the standards of specifications Mentioned under current monographs of USP/EP/BP

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Mr. Vikas Pathak	Mr. Vimal Patel	Mr. Niraj Choudhary
DESIGNATION	Officer QC	Assistant Manager QC	Assistant Manager QA/RA
SIGNATURE			
DATE	22/04/2020	22/04/2020	22/04/2020

R. N. LABORATORIES PVT. LTD.

Plot No.1 & 86, Sursez, Diamond Park, Sachin, Surat, Gujarat, India.

Certificate of Analysis

Section-B

Product Name	Chlorhexidine Gluconate 20 % Solution		
Reference	In house	AR. No.	MT/I/20/0283
Batch No.	RN1/CHG/20/20/149	Batch Size	8000 Kg
Mfg. Date	18/04/2020	Expiry date	17/04/2023
Release date	25/04/2020		

Section-A: Chemical testing Section-B: Microbial testing

ADDITIONAL TEST				
Sr. No	**Tests**	**Specification**	**Reference**	**Results**
1.	Microbial Enumeration Test			
	A. Total aerobic microbial count	NMT 10^2 CFU/ml	In house	Nil
	B. Total yeasts and molds count	NMT 10^2 CFU/ml	In house	Nil
	C. Other specific micro organism (*Serratia marcescens*)	Should be absent/10 ml	In house	Absent/10 ml

Note: The batch is released based on chemical analysis reported in Section - A, on completion of microbial tests results are reported in this Section - B.

Report: In the opinion of the undersigned, the above batch complies with the Current In house Specification.

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	Ms. Janvi Patel	Mr. Vimal Patel	Mr. Niraj Chaudhary
DESIGNATION	Trainee MB	Asst. Manager QC	Asst. Manager QA/RA
SIGNATURE	J.M.Patel		
DATE	25/04/2020	25/04/2020	25/04/2020